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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/534,292	05/09/2005	Karen Silence	A0848.70004US00	1144

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EXAMINER	
SZPERKA, MICHAEL EDWARD	

ART UNIT	PAPER NUMBER
1644	

MAIL DATE	DELIVERY MODE
09/28/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/534,292	SILENCE ET AL.	
	Examiner	Art Unit	
	Michael Szperka	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 May 2005*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9,15-28,30-33,35,37 and 39-63* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-9, 15-28, 30-33, 35, 37, and 39-63* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4)☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5)☐ Notice of Informal Patent Application
6)☐ Other: _____.

DETAILED ACTION

1. Applicant's preliminary amendments received May 9, 2005 are acknowledged.

Claims 10-14, 29, 34, 36, and 38 have been canceled.

Claims 2-9, 15-28, 30, 32, 33, 35, 39-51 have been amended.

Claims 52-63 have been added.

Claims 1-9, 15-28, 30-33, 35, 37, and 39-63 are pending in the instant application.

Election/Restrictions

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claims 15 and 16, drawn to methods of administering single domain antibodies that bind TNFα.

Group 2, claim 17, drawn to methods of administering single domain antibodies that bind CEA.

Group 3, claims 18 and 19, drawn to methods of administering single domain antibodies that bind EGFR.

Group 4, claims 20 and 27, drawn to methods of administering single domain antibodies that bind *H. pylori*.

Group 5, claims 21 and 27, drawn to methods of administering single domain antibodies that bind *M. tuberculosios*.

Group 6, claims 22 and 27, drawn to methods of administering single domain antibodies that bind influenza.

Group 7, claims 23 and 24, drawn to methods of administering single domain antibodies that bind MMP.

Group 8, claim 25 and 26, drawn to methods of administering single domain antibodies that bind INFγ.

Group 9, claim 52, 53, and 62, drawn to methods of administering single domain antibodies that bind IgE.

Group 10, claims 9, 30, 31, 46, and 51, drawn to single domain antibodies that bind EGFR.

Group 11, claim 32, drawn to single domain antibodies that bind LDLR.

Group 12, claim 32, drawn to single domain antibodies that bind FGF2R.

Group 13, claim 32, drawn to single domain antibodies that bind ErbB2R.

Group 14, claim 32, drawn to single domain antibodies that bind transferin.

Group 15, claim 32, drawn to single domain antibodies that bind PGDF.

Group 16, claim 32, drawn to single domain antibodies that bind VEGF.

Group 17, claim 32, drawn to single domain antibodies that bind PsmAR.

Group 18, claim 33, drawn to single domain antibodies that bind PDK1.

Group 19, claim 35, drawn to single domain antibodies that bind GSK1.

Group 20, claim 35, drawn to single domain antibodies that bind Bad.

Group 21, claim 35, drawn to single domain antibodies that bind caspase.

Group 22, claim 35, drawn to single domain antibodies that bind forkhead.

Group 23, claims 54-60 and 63, drawn to single domain antibodies that bind IgE.

Group 24, claim 37-45, drawn to methods of intracellular delivery of single domain antibodies.

Group 25, claim 50, drawn to nucleic acids encoding single domain antibodies that bind EGFR.

Group 26, claim 50, drawn to nucleic acids encoding single domain antibodies that bind LDLR.

Group 27, claim 50, drawn to nucleic acids encoding single domain antibodies that bind FGF2R.

Group 28, claim 50, drawn to nucleic acids encoding single domain antibodies that bind ErbB2R.

Group 29, claim 50, drawn to nucleic acids encoding single domain antibodies that bind transferin.

Group 30, claim 50, drawn to nucleic acids encoding single domain antibodies that bind PGDF.

Group 31, claim 50, drawn to nucleic acids encoding single domain antibodies that bind VEGF.

Group 32, claim 50, drawn to nucleic acids encoding single domain antibodies that bind PsmAR.

Group 33, claim 50, drawn to nucleic acids encoding single domain antibodies that bind PDK1.

Group 34, claim 50, drawn to nucleic acids encoding single domain antibodies that bind GSK1.

Group 35, claim 50, drawn to nucleic acids encoding single domain antibodies that bind Bad.

Group 36, claim 50, drawn to nucleic acids encoding single domain antibodies that bind caspase.

Group 37, claim 50, drawn to nucleic acids encoding single domain antibodies that bind forkhead.

Group 38, claim 61, drawn to nucleic acids encoding single domain antibodies that bind IgE.

3. Claims 1-8 link inventions 1-8 and claim 28 links inventions 10-22. The restriction requirement between the linked inventions is **subject to** the nonallowance of the linking claims, claims 1-8 and 28. Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions **shall** be withdrawn and

any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104 **Claims that require all the limitations of an allowable linking claim** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, the allowable linking claim, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

4. The inventions listed as Groups 1-38 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The technical feature that links the instant claimed invention is the use of single domain antibodies, such as those from camels, to treat disease. Frenken et al. in EP 0954978 disclose the use of camel single domain antibodies to treat various diseases (see entire document, particularly the abstract). As such, the technical feature of the instant invention does not make a contribution over the prior art of Frenken et al. and therefore the instant claimed inventions have been found to lack unity of invention.

5. Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

(a) the inventions have acquired a separate status in the art in view of their different classification;

(b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;

(c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);

(d) the prior art applicable to one invention would not likely be applicable to another invention;

(e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected invention**.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

7. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Szperka whose telephone number is 571-272-2934. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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September 18, 2007